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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09:546,085	04/10/2000	Allan Bradley	P01433US1	3389	
26271	7590 05/30/2003				
FULBRIGHT & JAWORSKI, LLP			EXAMINER		
1301 MCKIN SUITE 5100			CHUNDURU, SU	CHUNDURU, SURYAPRABHA	
HOUSTON, TX 77010-3095			ART UNIT	PAPER NUMBER	
			1637 DATE MAILED: 05/30/2003	14	

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary		Application No.	Applicant(s)			
		09/546,085	BRADLEY ET AL.			
		Examiner	Art Unit			
		Suryaprabha Chunduru	1637			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
THE - External control	MAILING DATE OF THIS COMMUNICATION. ensions of time may be available under the provisions of 37 CFR 1.1 r SIX (6) MONTHS from the mailing date of this communication. e period for reply specified above is less than thirty (30) days, a reply operiod for reply is specified above, the maximum statutory period varie to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing led patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply y within the statutory minimum of thirty (3 will apply and will expire SIX (6) MONTH , cause the application to become ABAN	y be timely filed 30) days will be considered timely. S from the mailing date of this communication. IDONED (35 U.S.C. § 133).			
Status	Deprenaise to communication(a) filed on 26 /	- hrunn, 2002				
1)⊠						
2a) <u> </u>	This action is FINAL . 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
<i>,</i> —	closed in accordance with the practice under cion of Claims					
4)🛛	Claim(s) 1-86 is/are pending in the application	l.				
	4a) Of the above claim(s) <u>42-62 and 65-77</u> is/are withdrawn from consideration.					
5)	Claim(s) is/are allowed.					
6)🛛	Claim(s) 1-41,63,64 and 78-86 is/are rejected.					
7)						
8) Claim(s) are subject to restriction and/or election requirement.						
Applicat	ion Papers					
9)☐ The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
	1. Certified copies of the priority documents have been received.					
	2. Certified copies of the priority documents have been received in Application No					
* ;	 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
14) 🔲 .	14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).					
a) ☐ The translation of the foreign language provisional application has been received. 15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachmer	nt(s)					
2) Notice	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) _	5) Notice of Info	mmary (PTO-413) Paper No(s) ormal Patent Application (PTO-152)			

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DETAILED ACTION

1. Applicants' response to the office action (Paper No. 13) filed on February 26, 2003 has been entered and considered.

2. Claims 8-41, 63-64 are considered for examination in the previous office action and claims 42-62, 65-77 are non-elected and withdrawn from further consideration. Claims 78-86 are newly added and are considered for examination.

Response to arguments

- 3. Applicants' response to the office action (Paper No. 13) is fully considered and found persuasive in part.
- 4. With reference to the rejection under 35 USC 112, second paragraph, Applicants amendment and arguments are fully considered and the rejection is with drawn herein in view of the amendment (Paper No. 13).
- 5A. The following is the rejection made in the previous office action under nonstatutory double patenting:

Claims 8, 13-17, 22-25, 27, 31-34, 37, 39-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7-10, 18-20, 25-28, and 33-34 of U.S. Patent No.6,048,695 ('695). Although the conflicting claims are not identical, they are not patentably distinct from each other because the biological molecule of the instant claims encompasses nucleic acids as claimed in the patented claims ('695). Biological molecule comprises a nucleic acid (DNA or RNA), a protein, or a peptide, lipid or a polysaccharide molecule. Further, the compound used to modify a nucleic acid of the patented claims has the said formula as claimed in the instant claims. The instant claims differ from

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patented claims only in reciting 'biological molecule' in place of 'nucleic acid' which is an obvious variation of the term nucleic acid. Further the high-density microarray disclosed in the patented claims is recited as microarray in the instant claims. Therefore, the instant claims are not patentably distinct and hence are rejected under obviousness-type double patenting.

Response to Arguments:

Applicants' arguments are considered and the rejection is maintained since Applicants' did not submit a terminal disclaimer. The newly added claims 78-86 are also rejected under nonstatutory double patenting over the said patent (USPN.6,048,695) herein because the patented claims 1-23, 25-28, 33-34, 51 encompass the instant claims. Therefore the instant claims are rejected as being obvious over the claims in the said patent.

5B. The following is the rejection made in the previous office action under statutory double patenting:

Claims 8-25, and 27-32 rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, 8-11, 18, 20-28, and 54 of prior U.S. Patent No. 09/853, 343. This is a double patenting rejection.

Response to Arguments:

Applicants' arguments are fully considered and found persuasive. However, the instant claims along with the newly added claims of the instant application are rejected under nonstatutory double patenting as discussed below.

- 6A. The following is the rejection made in the previous office action under 102(b):
- a. Claims 8-9, 12-18, 21, 23-24, 63-64, 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Krinski et al. (USPN. 4,713, 116).

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Krinski et al. teach a modified biological molecule (protein) wherein Krinski et al. teach that the modified biological molecule comprises a biological molecule covalently bound to a compound having formula R₁-X-R₂ and the compound could be glycodoxypropyltrimethoxysilane (see column 3, lines 8-10, column 4, lines 31-41). Krinski et al. also teaches that the modified biological molecule could be a protein material, a peptide or a polypeptide (see column 4, lines 31-53); the alkoxysilane could be a propyltrimethoxy silane (see column 4, lines 31-41); and could include addition of amino groups to the modified biological molecule (see column 4, lines 54-67). Thus, the disclosure of Krinski et al. meets the limitations in the instant claims.

Response to arguments:

Applicants' arguments are fully considered and found persuasive in part. Applicants agree that Krinski et al tech only modifying protein materials with organosilanes such as the alkoxysilane 3-glycidoxypropyltrimethoxysilane. Thus the instant claims 8, 12-16 are anticipated by Krinski et al. The instant claim recites "a composition comprising, an antibody or a small molecule" which meets the limitations in the prior art, because an antibody is a protein and a small molecule could comprise any polypeptide, or protein material. Applicants' argument regarding no suggestion or teaching of adding an amino group is fully considered and found persuasive. Hence the instant claims 9, 17-18, 21, 23-24 are not anticipated by Krinski et al. and therefore the rejection over these instant claims 9, 17-18, 21, 23-24 are with drawn herein. However the rejection is maintained herein for the instant claims 8, 12-16.

The new claim 84 is also rejected under 35 USC 102(b) as anticipated by Krinski et al. because the claim limitations meet the teaching as disclosed by Krinski et al. as discussed in the

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above rejection and Krinski et al. teach a solid support on which the said biological molecule is bound or immobilized (see column 8, lines 14-32).

6B. The following rejection is made in the previous office action under 35 USC 102(b):

(b) Claims 25, and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Plueddemann (USPN. 4,231,910).

Plueddemann teaches a modified biological molecules (primer compositions) on a solid support wherein Plueddemann discloses a solid support and immobilized modified biological molecules (see column 3, lines 22-29). Plueddemann also teaches that (i) the solid support comprises glass, quartz, aluminum, titanium, and metal oxides (see column 3, lines 22-29); and (ii) solid support could also comprise polyesters, polycarbonates, polyethelene terephthalate, and nylon (column 3, lines 30-54). Thus the disclosure of Plueddemann meets the limitations in the instant claims.

Response to arguments:

Applicants' arguments and amendment are fully considered and the rejections are withdrawn in view of the amendment (Paper No. 13).

- 6C. The following rejections were made in the previous office action under 35 USC 102(e):
- (c) Claims 8-9, 12, 15, 17-18, 21-22, 25-29, 31-32, and 78-81 are rejected under 35 U.S.C. 102(e) as being anticipated by Beattie (USPN. 6,426,183).

Beattie teaches microarrays comprising modified biological molecules wherein Beattie discloses that the microarray comprises (i) a solid support and (ii) a modified biological molecule (oligonucleotides) immobilized to said solid support (see column 3, lines 1-4). Beattie also disclose that (i) the solid support comprises silane containing substrates which include hydroxyl

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groups (see column 4, lines 46-54, column 3, lines 5-9); (ii) solid support comprises glass, quartz, metal oxides (see column 4, lines 13-36); and (iii) biological molecules on solid support are immobilized in discrete spots at a suitable distance from one another, typically from about 0.01 to 10mm of one another (see column 12, lines 25-31). Thus the disclosure of Beattie meets the limitations in the instant claims.

Response to arguments:

Applicants' arguments and amendment are fully considered and found not persuasive. Applicants' particular argument that Beattie did not teach a biological compound having at least an amino group and hydroxy group attached to a silane containing substrate, is found not persuasive because Beattie does teach attaching a modified compound comprising at least an amine and hydroxy group (e.g. aminopropanol containing compound) to a silaceous or silane-containing substrate (see abstract of the patent 6, 426, 183, column 2, lines 35-52). Thus the disclosure of Beattie meets the limitations in the instant claims and the rejection is maintained herein.

Further instant claims 8-9, 12, 15, 17-18, 21-22, 78-81 are rejected herein under 35 USC 102(e) as anticipated by Beattie because as discussed in the above rejection the instant claim limitations are taught by Beattie. Beattie also discloses that the modified biological compound comprises DNA, peptides, or a protein (see column 7, lines 34-67). Thus the disclosure of Beattie also meets the limitations in the instant claims.

New Grounds of rejections

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-41, 63-64, 78-88 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-56, 84-102 of copending Application No. 09/853, 343. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a composition comprising a nucleic acid, a polysaccharide or a saccharide, a lipid, an antibody or a small molecule covalently bound to a compound having the formula: R₁- X - R₂, wherein R₁ is a cyclic ether group, - R₂, is an alkoxysilane group; and X is a moiety linking the cyclic ether group and the alkoxysilane group. The claims in the co-ending applications encompass the instant claims. The instant claims differ from the claims in the co-pending application only in reciting "R₁ as a cyclic ether group or an amino group", which is an obvious variation. Further the high-density microarray disclosed in the claims of the co-pending application encompass the instant claims. Therefore, the instant claims are not patentably distinct over the claims in the co-pending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17, 21-29, 79-80 are rejected under 35 U.S.C. 102(e) as being anticipated by Gray et al. (5,851, 769).

Gray et al. teach a modified biological molecule (nucleic acid) and a solid support wherein Gray et al. teach that the modified biological molecule comprises a biological molecule covalently bound to a compound having formula R₁-X-R₂, wherein R₁ is an amino group, R₂ is an alkoxysilane group, X is a linking moiety, and the compound includes 3-aminopropyl triethoxysilane (see column 19, lines 32-48, column 8, lines 54-64). Gray et al. also teaches that the solid support to which the said biological molecule is attached comprises a glass, or a mica or a metal oxide surface (see column 19, lines 49-67, column 20, lines 1-6). Thus the disclosure of Gray et al. meets the limitations in the instant claims.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabna Chunduru May 28, 2003

> JEFFREY FREDMAN PRIMARY EXAMINER

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